IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Docket No.: 79731.010100
STANGEL, Peter	Confirmation No.: 1200
Serial No.: 09/772,394	Art Unit: 3626
Filing Date: January 1, 2001	Examiner: COBANOGLU, Dilek B
Title: CLINICAL CARE UTILIZATION MANAGEMENT SYSTEM	

RESPONSE UNDER 37 CFR §1.111

Commissioner for Patents
P.O. Box 1450
Mail Stop Amendment
Alexandria, VA 22313-1450

Sir:

     In response to the outstanding office action in the referenced application, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Arguments / Remarks begin on page 12 of this paper.

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

1–36. (Canceled)

37. (Previously Presented) A method for collecting patient clinical encounter information comprising the steps of:

storing, on a computer-readable medium operatively connected to a server, computer-executable instructions comprising:

a)   a navigation module;

b)   a verification module; and,

c)   a user interface comprising a plurality of fields, at least one of the fields comprising a pop-up list, the arrangement of the plurality of fields being fixed and arranged as on a clinical chart;

transmitting, via a network, the navigation module, the verification module and the user interface from the server to a client device;

causing the client device to display the user interface, including the plurality of fields, within a single screen to a user, the user interface facilitating the entry of patient clinical encounter information into the plurality of fields by not requiring the user to scroll the user interface within the single screen;

receiving, via the user interface displayed on the client device, patient clinical encounter information from the user;

causing the navigation module on the client device to modify the contents of at least one of the plurality of fields in response to the received patient clinical encounter information;

receiving, via the user interface displayed on the client device, at least one diagnosis selected by the user via the user interface;

causing the verification module on the client device, to determine an authorization level for the at least one diagnosis by referring to the contents of at least a subset of the plurality of fields; and,

receiving on the server, via the network, the patient clinical encounter information and the at least one diagnosis from the client device after the determination of the authorization level for the at least one diagnosis by the verification module.

38. (Previously Presented) The method of claim 37, the computer-executable instructions stored on the computer-readable medium and transmitted to the client device further comprising instructions for one or more criteria corresponding to a diagnosis, the criteria being displayed to the user in at least one of the plurality of fields.

39. (Previously Presented) The method of claim 38, the computer-executable instructions stored on the computer-readable medium and transmitted to the client device further comprising instructions for determining of an authorization level by referring to the criteria.

40. (Previously Presented) The method of claim 37, the computer-executable instructions stored on the computer-readable medium and transmitted to the client device further comprising instructions for a rule database, the rule database being employed by the verification module when determining the authorization level on the client device.

41. (Previously Presented) The method of claim 40, the rule database storing at least two levels of rules, the levels comprising:

a criteria level, the criteria level rules determining a criteria status by referring to data from at least one of the plurality of fields; and,

a diagnosis level, the diagnosis level rules determining a diagnosis authorization level by referring to the criteria status of at least one criteria level rule.

42. (Previously Presented) The method of claim 37, at least a subset of the plurality of fields being related in a hierarchical manner, the navigation module changing the content of at least one of the plurality of fields based on selections made therein by the user.

43. (Previously Presented) The method of claim 42, the verification module further comprising a plurality of criteria rules, the verification module evaluating the criteria rules to determine whether the patient clinical encounter information meets one or more criteria for determining an authorization level.

44. (Previously Presented) The method of claim 37, the instructions being transmitted via the Internet.

45. (Currently Amended) A method for facilitating the submission of a clinical record for automated processing, comprising the steps of:

   storing, on a computer-readable medium operatively connected to a server, computer-executable instructions comprising:

      a)   a navigation module;

      b)   selection interface comprising a plurality of fields within a single <u>screen</u>, the selection interface facilitating selection by the user of a plurality of predetermined clinical data types, the predetermined clinical data types comprising data necessary for creating at least a record of the symptoms associated with a patient and a diagnosis;

   transmitting, via a network, the navigation module and the selection interface from the server to a client device;

   causing the client device to display the selection interface to a user;

   receiving a selection from the selection interface; and,

   causing the navigation module on the client device to add~~ing~~ at least one data field in response to the selection, the data field being selected by a navigation module, to the displayed selection interface, the data field being quantified and associated with an objective criteria, the data field facilitating automated processing of the clinical record.

46. (Previously Presented) The method of claim 45, the selection interface and at least one data field being provided via an HTML web page on the Internet.

47. (Previously Presented) Computer readable media having instructions for facilitating the submission of a clinical record for automated processing tangibly stored thereon, the instructions, when executed by a computer, comprising instructions for:

   receiving a diagnosis from a user via a user interface running on a client device;

   receiving a criteria selection from the user via the user interface, the criteria being selected from a pre-defined list of criteria associated with the diagnosis, the criteria associated with a rule required for confirming the diagnosis, the criteria associated with at least one finding;

   receiving data from the user via the user interface corresponding to at least a subset of the at least one finding associated with the user selected criteria;

   causing the client device to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received from the user;

   causing the client device to transmit the data received from the user to the server to facilitate creation by the server of an electronic clinic record based on the data.

48. (Previously Presented) The computer readable media of claim 47, the data being transmitted from the client to the server via the Internet.

49. (Previously Presented) Computer readable media having instructions for providing a user interface for entering data for evaluating a clinical encounter tangibly stored thereon, the instructions, when executed by a computer, comprising instructions for displaying a user interface, the user interface comprising an interactive set of lists, each of the lists in the interactive set of lists having its own domain, and each of the lists in the interactive set of lists being displayed as a separate pop-up button list within a single screen, at least a subset of the lists being hierarchically related, the interactive set of lists being formatted to be similar to a clinical chart.

50. (Previously Presented) The computer readable media of claim 49, the user interface further comprising a display area, the display area displaying a parameter and at least one corresponding finding, each parameter being displayed proximate to the associated at least one finding.

51. (Previously Presented) The computer readable media of claim 49, the user interface further comprising a data entry area, the data entry area being adapted to facilitate entry of a plurality of findings for a parameter.

52. (Previously Presented) The computer readable media of claim 49, the interactive set of lists further comprising at least four pop-up button lists, the at least four pop-up button lists comprising at least one of each of an element pop-up button list, a system/group pop-up button list, a parameter pop-up button list, and a finding pop-up button list.

53. (Previously Presented) The computer readable media of claim 52, the instructions further comprising instructions for:

   relating the at least four pop-up button lists hierarchically; and

   receiving a selection in one pop-up list and populating at least the next lower pop-up button list in the hierarchy.

54. (Previously Presented) The computer readable media of claim 52, the instructions further comprising instructions for:

   receiving an entry in the element pop-up button list and populating the system/group pop-up button list with available entries;

   receiving an entry in the system/group pop-up button list and populating the parameter pop-up button list with available entries;

   receiving an entry in the parameter pop-up button list and populating the finding pop-up button list with available entries; and

   receiving an entry in the finding pop-up button list and performing one of:

   a)   entering the selecting finding with the selected parameter into a chart note data field in the user interface; and,

   b)   prompting the user to enter a numeric value associated with the finding and entering the finding, numeric value, and selected parameter into a chart note data field in the user interface.

55. (Previously Presented) The computer readable media of claim 54, the instructions further comprising instructions for:

   receiving a selection in a criteria pop-up button list; and

   populating the element pop-up button list, system/group pop-up button list, parameter pop-up button list, and finding pop-up button list based upon the selection.

56. (Previously Presented) The computer readable media of claim 55, the instructions further comprising instructions for entering diagnosis-relevant data either by:

   receiving a criteria pop-up list selection and prompting the user to make a selection in the finding pop-up list; or

   receiving a criteria pop-up list selection and prompting the user to enter a numerical value.

57. (Previously Presented) The computer readable media of claim 56, the instructions further comprising instructions for:

   receiving a selection in an additional information pop-up list; and

   setting the element pop-up list, the system/group pop-up list, parameter pop-up list, and finding pop-up list based upon the selection.

58. (Currently Amended) A   method for collecting   patient clinical encounter information comprising the steps of:

   storing, on a computer-readable medium operatively connected to a server, computer-executable instructions comprising:

      a)   at least one form;

      b)   a first set of rules; and,

      c)   a second set of rules;

   transmitting, via a network, the at least one form, the first set of rules, and the second set of rules to a client device;

   causing the client device to display the at least one form;

configuring at least a first subset of the at least one form to apply the first set of rules to at least a first subset of inputs entered into the first subset of forms;

configuring at least a second subset of the at least one forms to apply the second set of rules to at least a second set of inputs entered into the second subset of forms;

receiving patient clinical encounter data from at least one user via the at least one form displayed on the client device;

causing the client device to process the received patient clinical encounter data on the client device in accordance with the first and second set of rules.

59. (Previously Presented) The method of claim 58, the first subset of forms and the second subset of forms being the same.

60. (Previously Presented) The method of claim 58, the first set of rules are further configured to be applied when the first subset of inputs is received and the second set of rules are further configured to be applied when the second subset of inputs is received.

61. (Previously Presented) The method of claim 58, the instructions being transmitted via the Internet.

62. (Previously Presented) Computer readable media having instructions for providing a facilitating the single screen submission of patient clinical encounter information tangibly stored thereon, the instructions, when executed by a computer, comprising instructions for:

providing a clinical element selection interface, the clinical element selection interface facilitating the selection of a clinical element, the clinical elements comprising at least one of history and exam;

providing a system/group selection interface, the system/group interface facilitating the selection of a system/group associated with the selected clinical element, the system/group interface being populated based upon the selected clinical element;

providing a parameter selection interface, the parameter selection interface facilitating the selection of a parameter associated with the selected system/group , the parameter selection interface being populated based upon the selected system/group;

causing a client device to display the clinical element selection interface, the system/group interface and the parameter selection interface within a single screen.

63. (Previously Presented) Computer readable media having instructions for determining the appropriateness of patient clinical encounter information tangibly stored thereon, the instructions, when executed by a computer, comprising instructions for:

causing a client device to display a criteria selection interface to a user, the criteria selection interface allowing the user to select a diagnosis-based criteria;

receiving diagnosis related data from the user;

causing the client device to apply a verification rule to the received diagnosis related data, the verification rule providing a verification result, the verification result providing an authorization level for each selected criterion in the criteria selection interface.

64. (Previously Presented) The computer readable media of claim 63, the instructions further comprising the client device retrieving the criteria selection interface from a server via the Internet.

65. (Previously Presented) The computer readable media of claim 63, the instructions further comprising instructions for presenting the criteria selection interface in a clinical format that is familiar to clinicians and healthcare reviewers.

66. (Previously Presented) The computer readable media of claim 63, the instructions further comprising instructions for displaying the criteria selection interface to the user within a single screen such that the user does not have to scroll within the single screen while selecting criteria.

67. (Previously Presented) Computer readable media having instructions for an electronic clinical record creation and review system tangibly stored thereon, the instructions, when executed by a computer, comprising instructions for:

causing a client device to display a user interface, the user interface prompting the user for clinically relevant inputs;

receiving clinically relevant inputs from the user, the clinically relevant inputs comprising a diagnosis and at least one patient symptom, the at least one symptom being clinically relevant to the diagnosis;

causing the client device to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received from the user;

causing the client device to verify, without interaction with a server, the diagnosis by ensuring that sufficient symptoms have been received to satisfy at least one authorization criteria, wherein the at least one authorization criteria has been set by a health care reviewing organization;

causing the client device to generate an electronic clinical record on the client device; and

causing the client device to transmit the electronic clinical record to the health care reviewing organization for review.

68. (Previously Presented) The computer readable media of claim 67, the instructions further comprising instructions for transmitting the electronic clinical record via the Internet.

ARGUMENTS / REMARKS

Claims 37-68 are pending in the application.

II.   Claim Rejections Under 35 U.S.C. 112, First Paragraph

Claims 37-46 and 58-61 stand rejected under 35 U.S.C. 112, First Paragraph. Applicants respectfully traverse.

Applicant respectfully asserts that no new matter was added by Applicant's Amendment of claims 37, 45 and 58 to recite "transmitting, via a network, the navigation module, the verification module, and the user interface from the server to a client device." The present invention can be configured to run as a web-based system. See, e.g., paragraphs [0016], [0030] and [0075]. In such embodiments, the client can download the user interface and modules from the server. See also Paragraph [0033], which is reproduced below:

[0033] FIG. 1 illustrates the logical arrangement of modules in a utilization system
in accordance with the invention. The modules include a user interface 20, a
navigation module 21, and a verification module 22. The user interface 20 generates
the user screens with which the user interacts to submit or review data. The user
interface is preferably coupled to a communication link (not shown) that receives
user commands and data from a network connection. In one embodiment, the
communication link is an Internet connection. In another embodiment, the
communication link is a local area network connection. In yet another embodiment,
the communication link is a mobile, wireless, remote Internet link. In yet another
embodiment, the communication link is a proprietary link.

III.   Claim Rejections Under 35 U.S.C. 103(a)

Claims 37-45 and 47-66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,047,259 to Campbell, et al. ("Campbell") in view of U.S. Patent No. 5,574,828 to Hayward, et al. ("Hayward".) Applicant respectfully traverses.

Claim 37 recites a method for collecting patient clinical encounter information. Computer-executable instructions comprising a navigation module, a verification module and a

user interface are stored on a computer-readable medium operatively connected to a server. The user interface comprises a plurality of fields, at least one of the fields comprising a pop-up list, the arrangement of the plurality of fields being fixed and arranged as on a clinical chart. The navigation module, the verification module and the user interface are transmitted from the server to a client device.

Significantly, in the claimed invention, the client device is caused to display the user interface, including the plurality of fields, within a single screen to a user, the user interface facilitating the entry of patient clinical encounter information into the plurality of fields by not requiring the user to scroll the user interface within the single screen. Patient clinical encounter information is received from the user via the user interface displayed on the client device. The navigation module on the client device is caused to modify the contents of the plurality of fields in response to the received patient clinical encounter information. At least one diagnosis is selected by the user via the user interface displayed on the client device. The verification module on the client device is caused to determine the authorization level for the at least one diagnosis by referring to the contents of the plurality of fields. The patient clinical encounter information and the at least one diagnosis are received by the server, via the network, from the client device after the determination of the authorization level for the diagnosis by the verification module.

The invention of claim 45 is a method for facilitating the submission of a clinical record for automated processing. Computer-executable instructions comprising a navigation module, a verification module and a selection interface are stored on a computer-readable medium operatively connected to a server. The selection interface comprises a plurality of fields within a single, the selection interface facilitating selection by the user of a plurality of predetermined clinical data types, the predetermined clinical data types comprising data necessary for creating at least a record of the symptoms associated with a patient and a diagnosis. The navigation module and the selection interface are transmitted, via a network, from the server to a client device. The client device is caused to display the selection interface to a user. A selection is received from the receiving a selection from the selection interface. The navigation module on the client device is caused to add at least one data field in response to the selection, the data field being selected by a navigation module, to the displayed selection interface, the data field being

quantified and associated with an objective criteria, the data field facilitating automated processing of the clinical record.

The invention of Claim 47 is a computer readable media having instructions for facilitating the submission of a clinical record for automated processing. A diagnosis is received from a user via a user interface running on a client device. A criteria selection is received from the user via the user interface, the criteria being selected from a pre-defined list of criteria associated with the diagnosis, the criteria associated with a rule required for confirming the diagnosis, the criteria associated with at least one finding. Data is received from the user via the user interface corresponding to at least a subset of the findings associated with the user selected criteria. The client device is caused to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received from the user. The client device is caused to transmit from the user to the server to facilitate creation by the server of an electronic clinic record based on the data.

Claim 49 recites a computer having instructions for providing a user interface for entering data for evaluating a clinical encounter. The user interface comprises an interactive set of lists, each of the lists in the interactive set of lists having its own domain, and each of the lists in the interactive set of lists being displayed as a separate pop-up button list within a single screen, at least a subset of the lists being hierarchically related, the interactive set of lists being formatted to be similar to a clinical chart.

Claim 58 recites a method for collecting patient clinical encounter information. At least one form, a first set of rules and a second set of rules are stored on a computer-readable medium operatively connected to a server. The forms, the first set of rules, and the second set of rules are transmitted by the server to a client device. The client device is caused to display the forms. A first subset of the forms are configured to apply the first set of rules to a first subset of inputs entered into the first subset of forms. A second subset of forms is configured to apply the second set of rules to at least a second set of inputs entered into the second subset of forms. Patient clinical encounter data is received from at least one user via the forms displayed on the client device. The client device is caused to process the received patient clinical encounter data on the client device in accordance with the first and second set of rules.

Claim 62 is directed to a computer readable media having instructions for providing a facilitating the single screen submission of patient clinical encounter information. A clinical element selection interface is provided, the clinical element selection interface facilitating the selection of a clinical element, the clinical elements comprising at least one of history and exam. A system/group selection interface is provided, the system/group interface facilitating the selection of a system/group associated with the selected clinical element, the system/group interface being populated based upon the selected clinical element. A parameter selection interface is provided, the parameter selection interface facilitating the selection of a parameter associated with the selected system/group, the parameter selection interface being populated based upon the selected system/group. A client device is caused to display the clinical element selection interface, the system/group interface and the parameter selection interface within a single screen.

Claim 63 is directed to a computer readable media having instructions for determining the appropriateness of patient clinical encounter information. A client device is caused to display a criteria selection interface to a user, the criteria selection interface allowing the user to select a diagnosis-based criteria. Diagnosis related data is received from the user. The client device is caused to apply a verification rule to the received diagnosis related data, the verification rule providing a verification result, the verification result providing an authorization level for each selected criterion in the criteria selection interface.

The Campbell reference describes a software system for managing a health care practice includes interactive software tools for conducting a physical exam, suggesting tentative diagnosis, and managing a treatment protocol. The physical exam software guides the user through a physical exam, prompting the user for input and dynamically generating context sensitive questions based on prior input. The diagnosis software generates a list of possible diagnoses based on the observations recorded from the physical exam. The user can interactively select a diagnosis by selecting a diagnosis from a rule out list and watching the display as the system dynamic updates the status of unresolved symptoms. The user can also select a treatment protocol, which is integrated with future physical exams. The treatment protocol is integrated such that future exam sessions reflect the status of the treatment protocol and remind the user which services need to be performed and when they should be performed.

Significantly, in Campbell, the diagnosis software uses the observations made during the medical examination to prepare a rule-out list and prescribe a treatment protocol. Diagnosis software running on the server uses the observations to generate a list of abnormal observations and tentative diagnosis. See, e.g., Campbell at Col. 7, lines 42-46. Processing of the medical data inputted into the data input terminals is performed solely on the processing system server. Cummings; Fig 3, column 7, lines 39-60.

In Campbell, multiple user interface screens, arranged in a hierarchy, are provided for conducting a medical exam. See, e.g., Campbell at Col. 12, line 59 to Col. 13, line 18. When the user clicks on any of these buttons, the system launches a new screen for the selected part of the physical exam. See Campbell at Col 12, line 59, to Col 13, line 20.

In Campbell, a diagnosis is selected after input of clinical data. Campbell's rule-out list is a list of possible diagnoses automatically generated by the server. The actual observations made during the physical examination are matched against the list of observations associated with ailments. Ailments which match are then added to the diagnosis rule out list. The doctor can select a diagnosis by clicking on an item in the rule out list. See Campbell at Col. 16, line 67 to Col 17 line 7. The diagnosis list is generated by the server and diagnosis is selected from a list by the user; this is a conclusionary action, and offers no process guidance for input of clinical data and for evaluation of the clinical input.

Furthermore, while the software described by Campbell does indeed utilize a rule set, Campbell's rules are server side, are not dynamically applied on the client side as clinical data is entered and are unrelated to each other. See, e.g., Campbell at Col 6, lines 23 to 25.

Hayward is directed to a system utilizing a software program used to write other software application programs for the implementation of guideline applications for use in situations where a qualification decision or next course of action determination must be made. The system uses questions with limited choice answers. Data provided in answer to the questions causes a second program application to be automatically generated based on the answers. The second application then elicits responses in an interactive manner. Qualification decisions and courses of action are suggested as an output of the second application. Means are provided for evaluating the reliability of the suggestions based on consistency of answers and fatigue of the user. Means are

also provided for editing either application program. In one embodiment, the system uses a pop-up for displaying a keyword list.

With respect to independent Claim 37, Campbell does not disclose transmitting, via a network, a navigation module, a verification module and a user interface having at least one pop-up list from the server to a client device. As noted above, diagnosis software <u>running on the server</u> uses the observations to generate a list of abnormal observations and tentative diagnosis. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. Collection of patient clinical encounter information is done entirely on the client (browser) side without interaction with the server. After all clinical encounter information has been collected, the information is then submitted to the server for storage. The interface in Campbell makes no use of pop-up lists.

Campbell does not disclose a verification module on the client device that determines an authorization level for at least one diagnosis. Rather, Campbell discloses a system where (a.) different functions may be assigned to different computers (Campbell, col. 5, lines 33-61) (b.) the authority to make diagnoses (and other perform other functions) can be limited to specific users (Campbell, col. 6, 21-46), and (c.) given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) In the present Application, the authorization level for a diagnosis is used to determine what level of treatment is authorized for any specific clinical event. For example, the verification module receives user data and concurrently, real-time determines whether the data is sufficient to authorize the clinical event or to satisfy a particular criteria of the clinical event. See, e.g. para. [0074] of the present application. Campbell discloses no such function.

As another example, the standard authorization level for a patient in the hospital is "acute level of care," however the authorization for a patient in an intensive care unit would be "intensive level of care." See, e.g. para. [0059] of the present application. Campbell discloses no such function.

Hayward does nothing to remedy the deficiencies of Campbell cited above. Specifically, Hayward does not disclose or suggest transmitting, via a network, a navigation module, a verification module and a user interface having at least one pop-up list from the server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs. Furthermore Hayward does not disclose a verification module on a client device that determines an authorization level for at least one diagnosis. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

The Examiner apparently cites Hayward, in part, for the general proposition that pop-up lists were known in the art at least as early as 1996. The same could be said for any other user interface element used in the present invention. It is the use of pop-up lists in the manner specifically described in the Application that is claimed, not the mere use of pop-up lists in the abstract. The Examiner has failed to particularly point out how Hayward renders the Applicant's use of pop-up lists *as claimed* obvious. The meaning of the Examiner's further statement that "[i]t would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Hayward with the motivation of generating [sic] second program automatically based on the answers to the questions" is not clear, since neither the present invention nor Campbell generate programs.

Furthermore, the Examiner has not advanced a sufficient rationale as to why a person skilled in the art would have been motivated to combine Campbell and Hayward in the manner described in the present Office Action. A factfinder should be aware of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. KSR Int'l Co. v. Teleflex, 127 S.Ct at 1742. In determining whether a claimed invention is an obvious combination of prior art references, it must be shown there is an apparent reason to combine the known elements in the fashion claimed. Id. at 1741. *To facilitate review, this analysis should be made explicit*. Id. No such analysis was provided.

Claim 45 and its dependants recite, *inter alia*, that the referenced navigation module and selection interface are stored on a computer readable medium operatively connected to a server, and that the navigation module, the verification module and the user interface are transmitted to a

client device where they enable a method for facilitating the submission of a clinical record for automated processing. Campbell does not disclose transmitting, via a network, a navigation module and a selection interface from the server to a client device. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. There is no discussion of any active transmission of program modules between server and client machines during the process of collecting patient encounter information.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 45. Specifically, Hayward does not disclose or suggest transmitting, via a network, a navigation module and a selection interface having at least one pop-up list from the server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs.

Claim 47 recites, *inter alia*, that user data is received via a user interface on a client device and that the client device verifies the data without interaction with a server. Campbell does not disclose a system having a criteria associated with rules required for confirming diagnoses that have been entered by a user. Rather, Campbell discloses a system wherein given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) Furthermore, Campbell does not disclose a system wherein a client device is caused to verify, without interaction with a server, that all necessary data associated with the diagnosis has been received from the user. Rather, Campbell discloses a system wherein client machines are in constant communication with a server. See, e.g. Campbell, col 14, ln 19-21 ("The data displayed in this and other exam screens is dynamic in that it is updated by the server soon after it is entered.")

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 47. Specifically, Hayward does not disclose or suggest a system having a criteria associated with rules required for confirming diagnoses that have been entered by a user.

The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to independent Claim 49, Campbell does not disclose, *inter alia*, sets of lists being displayed as a separate pop-up buttons lists within a single screen, the interactive set of lists being formatted to be similar to a clinical chart. Campbell, does not in fact, disclose the use of pop-up buttons at all. Furthermore, Campbell does not disclose an interface using lists hierarchically related to one another. With respect to the examples cited by the Examiner, Campbell, FIG. 10 and col. 17, ln. 46-52, discloses a diagnostic protocol screen with the patient banner, a tentative diagnosis box, recommended therapy box, a diagnosis status check list and navigational control buttons.

Only the recommended therapy "box" resembles a list, and is not hierarchically related to another list. Campbell, col. 12, line 59 to col. 13, line 20 describes physical exam buttons represent the top level in a hierarchy of physical exam *screens* wherein when the user clicks on any of these buttons, the system launches a new screen. There is no mention of hierarchically related *lists*. Campbell, col. 1, line 62 to col. 2, line 13, discusses, in general terms, a system that interactive user interface screens for conducting an interactive medical exam, generating diagnoses of abnormal observations, and managing a treatment protocol. There is no mention of hierarchically related *lists*.

Hayward does nothing to remedy the deficiencies of Campbell cited above. Specifically, Hayward does not disclose or suggest disclose sets of lists being displayed as a separate pop-up buttons lists within a single screen, the interactive set of lists being formatted to be similar to a clinical chart. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

Claim 50 recites the computer readable media of claim 49, the user interface further comprising a display area, the display area displaying a parameter and at least one corresponding finding, each parameter being displayed proximate to the associated at least one finding. The Examiner cites Campbell's Figure 5, and Col. 16, line 66 to Col. 17, line 7.

Campbell's Fig. 5 shows check boxes and drop down lists of questions. The Examiner's cited lines refer to a list of binary items which have been returned from the server to the client

after the physical exam has been completed. "Trouble Hearing-Yes", "Tartar on Teeth-Found" are binary items. Campbell does not describe a <u>clinical chart note format</u> of a finding with its parameter being displayed as the finding is being entered, or the capability of further modifying this parameter with additional findings. For example: Chest auscultation [parameter]; wheezing [finding]; ronchi [additional finding].

Independent Claim 58 and its dependants have been amended to more clearly state that the referenced form, first set of rules and second set of rules are stored on a computer readable medium operatively connected to a server, and that the form, first set of rules and second set of rules are transmitted to a client device where they enable a method for collecting patient clinical encounter information. Campbell does not disclose transmitting, via a network, at least one form, a first set of rules and second set of rules from the server to a client device. At most, Campbell discusses, in general terms, (a.) software implemented in a series of program modules executed either on a server or client computer that (b.) may be ported to other computer system configurations, and that (c.) program modules may be located in both local memory of a client computer and remote memory such as in the server computer. Campbell, col. 4, ln. 1-18. There is no discussion of any active transmission of program forms or rules between server and client machines during the process of collecting patient encounter information.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 58. Specifically, Hayward does not disclose or suggest transmitting, via a network, at least one form, a first set of rules and second set of rules from a server to a client device. In fact, Hayward makes no mention, whatsoever, of clients, server or networks and simply describes a software program used to write other software application programs.

With respect to independent Claim 62, Campbell does not disclose a system wherein client device is caused to display a clinical element selection interface, a system/group interface and a parameter selection interface within a single screen. With respect to the examples cited by the Examiner, Campbell, col. 13, line 66 to col. 14, line 8, and FIG. 5, discloses "graphical user interface controls prompt the user to enter information because they display an item to be observed and then give the user an option to make some observation for that item." In FIG. 5, the user can select the overall condition or temperature observation by checking a check button, enter numerical data such as temperature via a graphical box or enter or select text input from

drop-down boxes. The screen does not provide a clinical element selection interface, a system/group interface and a parameter selection interface.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 62. Specifically, Hayward does not disclose or suggest disclose a system wherein client device is caused to display a clinical element selection interface, a system/group interface and a parameter selection interface within a single screen. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to independent Claim 63, Campbell does not disclose a criteria selection interface wherein a verification rule is applied to a received diagnosis in order to determine an authorization level for each selected criterion in the criteria selection interface. Rather, Campbell discloses a system where (a.) different functions may be assigned to different computers (Campbell, col. 5, lines 33-61) (b.) the authority to make diagnoses (and other perform other functions) can be limited to specific users (Campbell, col. 6, 21-46), and (c.) given a set of symptoms, the system suggests a set of possible diagnoses (Campbell col. 16, ln. 65 - col. 17, ln. 10.) In the present Application, the authorization level for a diagnosis and each criterion is given as each clinical finding is entered.

Hayward does nothing to remedy the deficiencies of Campbell cited above with respect to independent Claim 63. Specifically, Hayward does not disclose or suggest a criteria selection interface wherein a verification rule is applied to a received diagnosis in order to determine an authorization level for each selected criterion in the criteria selection interface. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information.

With respect to claim 66, no *prima facie* basis for rejection has been given. Accordingly, the next Action by the Office cannot be a final rejection.

Claim 46 stands rejected under 35 U.S.C. 103(a) over Campbell in view of Hayward and further in view of U.S. Patent Publication No. 2001/0037218 A1 to Kaker et al. ("Kaker".) Applicant respectfully traverses.

Claim 46 depends on independent Claim 45 and is further directed to a system wherein the selection interface and at least one data field being provided via an HTML web page on the Internet.

Kaker discloses an online system for providing prescription assistance for indigent patients using programs provided by pharmaceutical manufacturers comprises a web server connected to the internet; a database connected to the web server, the database including names of manufacturers of drugs providing prescription assistance to indigent patients and their respective application forms required to be filled out to participate in the programs; at least one workstation connected to the web server through the internet; and software operably associated with the web server and the database for searching the database for application forms by a user located at the workstation by selecting manufacturer name or drug name, for viewing the forms on a monitor, for filling out the forms for a patient and printing the forms for sending to the manufacturer.

Kaker does not remedy the deficiencies of Campbell and Hayward discussed above with respect to Claim 45 Specifically Neither Campbell nor Hayward nor Kaker disclose or suggest transmitting, via a network, a navigation module and a selection interface from a server to a client wherein the selection interface facilitates selection by the user of a plurality of predetermined clinical data types, the predetermined clinical data types comprising data necessary for creating at least a record of the symptoms associated with a patient and a diagnosis.

Claims 67 and 68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell and Hayward in view of U.S. Patent No. 5,301,105 to Cummings, Jr. ("Cummings"). Applicant respectfully traverses.

Independent Claim 67 has been amended to more clearly state that the client device verifies diagnoses without interaction with a server and that that the criteria used to verify diagnoses on the client device are set by health care reviewing organization that receive transmission of electronic clinical records relating to the diagnoses.

Independent Claim 67, as amended, is computer readable media having instructions for an electronic clinical record creation and review system. A client device is caused to display a user interface, the user interface prompting the user for clinically relevant inputs. Clinically

relevant inputs are received from the user, the clinically relevant inputs comprising a diagnosis and at least one patient symptom, the symptom being clinically relevant to the diagnosis. The client device is caused to verify, without interaction with a server, the diagnosis by ensuring that sufficient symptoms have been received to satisfy at least one authorization criteria, wherein the at least one authorization criteria has been set by a health care reviewing organization. The client device to is caused to generate an electronic clinical record on the client device and to transmit the electronic clinical record to the health care reviewing organization for review.

Cummings describes a fully integrated and comprehensive health care system that includes the integrated interconnection and interaction of the patient, health care provider, bank or other financial institution, insurance company, utilization reviewer and employer so as to include within a single system each of the essential participants to provide patients with complete and comprehensive pre-treatment, treatment and post-treatment health care and predetermined financial support therefor.

Neither Campbell nor Hayward nor Cummings disclose or suggest a system wherein a client device is caused to verify, without interaction with a server, a diagnosis by ensuring that sufficient symptoms have been received to satisfy at least one authorization criteria, wherein the at least one authorization criteria has been set by a health care reviewing organization. The Examiner acknowledges that Campbell fails to expressly teach transformation of physical patient charts into clinically formatted electronic charts for review by health care review organizations. The system in Hayward relates to automatic generation of computer programs and provides no functionality, whatsoever, that relates to entry of medical information. Cummings merely stands for the proposition that an integrated medical system may be in communication with an insurance company, but does not discuss client systems which use, without interaction with a server, authorization criteria supplied by a health care reviewing organization to verify diagnoses.

It is well established that, in order to show obviousness, all limitations must be taught by the prior art. In Re Royka, 180 U.S.P.Q. 580, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. It is error to ignore specific limitations distinguishing over the references. In Re Boe, 184 U.S.P.Q. 38, 505 F.2d 1297 (CCPA 1974); In Re Saether, 181 U.S.P.Q. 36, 492 F.2d 849 (CCPA 1974); In Re Glass, 176 U.S.P.Q. 489, 472 F.2d 1388 (CCPA 1973).

Since, as argued above, independent Claims 37, 45, 47, 49, 58, 62, 63 and 67 contain elements neither expressly or inherently described by any of the cited references, independent Claims 37, 45, 47, 49, 58, 62, 63 and 67 and their dependant claims are patentable over any combination of the cited references. Therefore, Applicant respectfully requests that the rejections of Claims 37-68 under 35 U.S.C. 103(a) be withdrawn.

IV.   Conclusion

Having responded to all objections and rejections set forth in the outstanding Office Action, it is submitted that claims 37-68 are in condition for allowance and Notice to that effect is respectfully solicited. In the event that the Examiner is of the opinion that a brief telephone or personal interview will facilitate allowance of one or more of the above claims, the Examiner is courteously requested to contact applicant's undersigned representative.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 50-2638. If an extension of time is required, this should be considered a petition therefor.

Respectfully submitted,

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